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<u>L3</u>	(human adj monoclonal) and (Cd40) and (transgenic)	101	<u>L3</u>
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L2: Entry 13 of 13

File: USPT

Oct 7, 1997

DOCUMENT-IDENTIFIER: US 5674492 A

TITLE: Method of preventing or treating disease characterized by neoplastic cells expressing CD40

Detailed Description Text (39):

Binding proteins may also be constructed utilizing recombinant DNA techniques to incorporate the variable regions of a gene which encodes an antibody to CD40. (see James W. Larrick et al., "Polymerase Chain Reaction Using Mixed Primers: Cloning of Human Monoclonal Antibody Variable Region Genes From Single Hybridoma Cells," Biotechnology 7:934-938, Sep. 1989; Reichmann et al., "Reshaping Human Antibodies for Therapy," Nature 332:323-327, 1988; Roberts et al., "Generation of an Antibody with Enhanced Affinity and Specificity for its Antigen by Protein Engineering," Nature 328:731-734, 1987; Verhoeyen et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity," Science 239:1534-1536, 1988; Chaudhary et al., "A Recombinant Immunotoxin Consisting of Two Antibody Variable Domains Fused to Pseudomonas Exotoxin," Nature 339:394-397, 1989).

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L2: Entry 12 of 13

File: USPT

Sep 1, 1998

DOCUMENT-IDENTIFIER: US 5801227 A

TITLE: Antibodies to CD40

Detailed Description Text (10):

Similarly, binding proteins may also be constructed utilizing recombinant DNA techniques to incorporate the variable regions of a gene which encodes a specifically binding antibody that blocks binding of CD40 to CD40L. The construction of these proteins may be readily accomplished by one of ordinary skill in the art (see James W. Larrick et al., "Polymerase Chain Reaction Using Mixed Primers: Cloning of Human Monoclonal Antibody Variable Region Genes From Single Hybridoma Cells," *Biotechnology* 7:934-938, September 1989; Riechmann et al., "Reshaping Human Antibodies for Therapy," *Nature* 332:323-327, 1988; Roberts et al., "Generation of an Antibody with Enhanced Affinity and Specificity for its Antigen by Protein Engineering," *Nature* 328:731-734, 1987; Verhoeyen et al., "Reshaping Human Antibodies: Grafting an Antilysozyme Activity," *Science* 239:1534-1536, 1988; Chaudhary et al., "A Recombinant Immunotoxin Consisting of Two Antibody Variable Domains Fused to Pseudomonas Exotoxin," *Nature* 339:394-397, 1989), given the disclosure provided herein. Briefly, the antigen-binding sites or CD40 binding domain from a cell which produces a specifically binding and blocking monoclonal antibody are amplified, and inserted directly into the genome of a cell which produces human antibodies (see Verhoeyen et al., supra; see also Reichmann et al., supra). This technique allows the antigen-binding site of a specifically binding murine or rat monoclonal antibody to be transferred into a human antibody. Such antibodies are preferable for therapeutic use in humans because they are not as antigenic as rat or mouse antibodies. Alternatively, the antigen-binding sites (variable region) may be either linked to, or inserted into, another completely different protein (see Chaudhary et al., supra), resulting in a new protein with antigen-binding sites of the antibody as well as the functional activity of the completely different protein. As one of ordinary skill in the art will recognize, the antigen-binding sites or CD40 binding domain of the antibody may be found in the variable region of the antibody. Furthermore, DNA sequences which encode smaller portions of the antibody or variable regions which specifically bind to mammalian CD40 may also be utilized within the context of the present invention. These portions may be readily tested for binding specificity to the CD40 utilizing assays known in the art, including for example ELISA, ABC, or dot blot assays.

Detailed Description Text (15):

Purified antibodies or binding proteins may also be utilized therapeutically to block the binding of CD40-L to CD40 in vivo, or for in vivo neutralization of CD40 bearing cells. In preferred embodiments, the antibody is modified to escape immunological detection, for example, by transferring the antigen-binding site of a specific murine monoclonal antibody to a human monoclonal antibody, as discussed above. Particularly preferred is the use of therapeutic compositions comprising an antibody or binding protein to CD40, and a physiologically acceptable carrier or diluent. Suitable carriers or diluents include, among others, neutral buffered saline or saline mixed with nonspecific albumin. Additionally, the therapeutic composition may include further excipients or stabilizers such as buffers, carbohydrates including, for example, glucose, sucrose, or dextrose, chelating agents such as EDTA, or various preservatives. Appropriate dosages may be determined in clinical trials, although the amount and frequency of administration may be dependent on such factors as the nature and severity of the indication being treated, the desired response, and the condition of the patient.